REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Applicants note that the lack of unity finding has been made final and that claims 1, 4-5, 12 and 23 are under examination.

The objections to claims 1, 12 and 23 have been overcome in view of the above amendments. Support for new claims 45-48 is found at page 6, lines 19 - 25 and page 5, lines 27 - 26. Support for new claim 49 is found at page 22, line 29 - page 30, line 2. Support for new claims 50-51 is found at page 25, lines 9 - 15.

The rejections of claims 4 and 12 for indefiniteness are respectfully traversed in view of the above amendments. Applicants further point out that the interacting polypeptide comprises SEQ ID NO: 23 and the substrate polypeptide comprises SEQ ID NO: 30, accordingly it is clear in the claims which polypeptide is covered.

The rejection of claims 1, 4-5, 12 and 23 under 35 U.S.C. §112 (first paragraph) for lack of written description is respectfully traversed.

The specification as filed satisfies the written description requirement for the claims. In particular, page 4, line 11- page 8, line 2 fully describes the PDK1 of the present invention. Further, the specification on page 3, lines 1-17 describes PRK2 and the interacting polypeptide. Further, a large number of species are listed that define the claimed genus (see specification, page 51, lines 11-21 and page 41, line 1 *et seq*).

Firstly, it is the position of the U.S. Patent & Trademark Office ("PTO") that the specification discloses a

genera of products merely defined by function (outstanding office action, page 5). Applicants respectfully disagree.

With respect to PDK1, said protein kinases are fully described in the specification as filed. See specification on page 4, line 11- page 5, line 15 for a full discussion of PDK1 as well as its structure and function. In addition, as set out in the references cited in the specification page 4, line 11- page 5, line 15, and page 3, lines 1 - 6, the term PDK1 was discussed by the prior art. What is already known does not have to be repeated in detail in the specification (Manual of Patent Examining Procedure ("MPEP") 2163 II.A.2). Accordingly, the claims as relating to PDK1 do not lack written description.

With respect to PRK2, said protein kinase is defined in the specification page 3, lines 10-14. In addition, the sequence of human PRK2, for example, is given in Figure 11. Accordingly, for the reasons listed in the paragraph above with respect to PDK1, the claims as relating to PRK2 do not lack written description.

With respect to the "interacting polypeptide", firstly the U.S. Patent and Trademark Office has asserted that "a polypeptide . . . which only needs to comprise basically 6-7 amino acids of a full-length polypeptide . . . is totally incapable of retaining its appropriate three dimensional structure such that it can interact with PDK1 or its derivatives." (Office action page 6). Applicants respectfully assert that the PTO has provided no basis for this statement. Further, in contrast to this statement, the specification provides examples of relatively small peptides which operate as interacting polypeptides (see page 51, lines 11-21 and page 45 *et seq* (small polypeptide fused to GST)). Further, pages 8, line 26 - page 9, line 2; page 10, line 27 - page 11, line

7 and page 11, line 24 - page 12, line 13 describe other examples of interacting polypeptides.

Applicants submit that the PTO is employing the improper standard in determining whether the application as filed complies the written description requirement of 35 USC § 112(first paragraph).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the invention at the time the application was filed (Manual of Patent Examining Procedures ("MPEP") 2163). Possession may be shown in a variety of ways including a description of distinguishing identifying characteristics sufficient to show that the applicant was in possession of the invention (MPEP 2163 I). There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed (MPEP I.A) An actual reduction to practice is not required (2163.). Further, there is no requirement that the features of the invention must be defined by structure and function (Id.). As detailed above, the claimed invention was described in sufficient detail to meet the written description requirement. Further, the limitations of the claims to which the PTO objects are contained in the claims as filed.

With particular respect to a claim drawn to a genus, the written description requirement for a claimed genus may be satisfied through description of a representative number of species by a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus (Id.). There may be situations where one species is a "representative number of species" (Id.). Satisfactory disclosure depends on whether one of ordinary

skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed (Id.).

In the present patent application, as filed, the claimed invention is described in sufficient detail to allow one of ordinary skill in the art to recognize that applicants had possession of the claimed interacting polypeptide having the distinguishing characteristics of (1) comprising SEQ ID NO: 25 and (2) altering the substrate specificity of PDK1. Accordingly, the rejection of the claims for lack of written description is improper and should be withdrawn.

The rejection of claims 1, 4, 12 and 23 under 35 U.S.C. §112 (first paragraph) for lack of enablement is respectfully traversed.

In order for claims to be enabled, the specification, when filed, must contain sufficient information as to enable one skilled in the art to make and use the claimed invention. (Manual of Patent Examining Procedure ("MPEP") 2164.01). As long as the specification discloses at least on method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, the enablement requirement is satisfied. (In re Fisher, 427 F.2d. 833, 839, 166 USPQ 18, 24 (CCPA 1970); MPEP 2164.01(b)). In determining whether a patent application is in compliance with the enablement requirement, the PTO will consider whether one of ordinary skill in the art could practice the invention without undue experimentation. In re Wands, 858 F.2d. 731, 8 USPQ2d 1400 (Fed. Cir. 1988)).

In the present application as filed, one skilled in the art was given sufficient information to practice the claimed invention. With respect to the claimed "substrate polypeptide" of claims 4 and 12, one skilled in the art, with

the knowledge contained in the application as filed, could have readily determined whether any particular polypeptide contained the consensus amino acid sequence identified, for example, by looking for this sequence in the deduced amino acid sequence of any protein in a protein database. Such a procedure is well within the skill of the art. Such a procedure does not require undue experimentation. Further, even an extensive period of experimentation may not be undue, if the skilled artisan is given sufficient direction and guidance (MPEP 2164.06). Here, the specification gives guidance as to the required consensus sequence as well as to the method of claim 4, where a residue of the consensus sequence is phosphorylated by exposing the substrate polypeptide to PKD1.

With respect to the interacting polypeptide of claims 1 and 23, as discussed above with respect to written description, numerous species of the interacting polypeptide which include SEQ ID NO:25 are included in the specification as filed. Accordingly, it would be well within the skill of one skilled in the art to determine the interacting polypeptides as claimed. These interacting polypeptides where shown to alter the substrate specificity of PDK1 (page 45, lines 1-17, page 51, lines 11 - 21). It is well within the skill of one skilled in the art to obtain other interacting polypeptides which include the claimed SEQ ID NO:25 and to determine whether the polypeptide alters the substrate specificity of PDK1 (see specification, for example, page 48, line 6 *et seq*, where a simple test to determine if the substrate specificity of PDK1 is altered).

As discussed above, although some experimentation may be required, such experimentation is not undue. Even an extensive period of experimentation may not be undue, if the skilled artisan is given sufficient direction and guidance

(MPEP 2164.06). Such guidance is contained in the specification as filed.

Thus, because the claims of the present application are enabled, the rejection for lack of enablement must be withdrawn.

Applicants note that five of the references listed on the PTO-1449 form submitted on October 30, 2002 were not initialed. Applicants have resubmitted these references (shown on the attached PTO-1449 form). Because these references were previously submitted to the PTO, applicants believe that no fee is due. However, the Commissioner for Patents is hereby authorized to charge any fee that may be due to Deposit Account 50-0772.

In view of the foregoing, applicants believe the present case to be in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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Date

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